

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

Comparison between therapeutic effects of methylphenidate with risperidone in methamphetamine dependent patients

Protocol summary

2012-04-16, 1391/01/28

Summary

In this experimental study 60 methamphetamine-dependent patients admitted to addiction clinics or psychiatric clinics in the city was selected after completing an informed consent to participate in the study by the patient or guardian him, Randomized to two groups: standard treatment (risperidone) and intervention (methylphenidate) are divided. Inclusion criteria: Methamphetamine dependence (More than 10 times the regular use of methamphetamine or 10 days); Positive Methamphetamine urine test; Age 18-65; no dependency to other opioid and opium; Exclusion criteria: seizure; tardive dyskinesia or tic; gravidity; past history of methylphenidate craving; past history of diabetes or MI; In the first and last study completed questionnaires contained demographic information and past history and physical exam and psychological exam. This information contains patients and sleep and daily activity and psychotic reaction and craving. The patients devised two groups (standard treatment and intervention). Standard group give risperidone 1mg during 1 week, then 1mg/bid during 3 weeks. Intervention group give methylphenidate 10mg/day during 2 weeks, then 7.5 mg/day during 1 week, then 5 mg/day during 1 week. Both groups information is calculated than therapeutic effect comparison is analysed.

Registrant information

Name

Akram Rasti Barzoki

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Tavana clinic

Expected recruitment start date

2012-01-21, 1390/11/01

Expected recruitment end date

2012-09-20, 1391/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between therapeutic effects of methylphenidate with risperidone in methamphetamine dependent patients

Public title

Comparison between therapeutic effects of methylphenidate with risperidone in crystal dependent patients

Purpose

Treatment

Inclusion/Exclusion criteria

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202159018N1**

Registration date: **2012-04-16, 1391/01/28**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

Inclusion criteria: Methamphetamine dependence (More than 10 times the regular use of methamphetamine or 10 days); ; Positive Methamphetamine urine test ; Age 18-65 ; note dependency to other opioid and opium ; Exclusion : seizure; tardive dyskinesia or tic; gravidity; past history of methyl phenidate craving; past history of diabetes or MI; past history of allergy to risperidone; past history of suicide; under treatment by anti psychotic drug or mood stabilizer or inhibitor CYP2D6 drugs

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

medical university

Street address

sardasht site

City

arak

Postal code

Approval date

2012-02-06, 1390/11/17

Ethics committee reference number

901205

Health conditions studied

1

Description of health condition studied

methamphetamine dependency

ICD-10 code

T43.6

ICD-10 code description

T43.6

Primary outcomes

1

Description

craving

Timepoint

before and during and after intervention

Method of measurement

psychological exam

2

Description

sleep condition improve

Timepoint

before and during and after intervention

Method of measurement

Beck questionnaire

3

Description

psychotic reaction

Timepoint

before and during and after intervention

Method of measurement

Beck questionnaire and psychological exam

Secondary outcomes

empty

Intervention groups

1

Description

standard group give risperidone 1mg during 1 week, then 1mg/bid during 3 weeks

Category

Treatment - Drugs

2

Description

intervention group give methylphenidate 10mg/day during 2 weeks, then 7.5 mg/day during 1 week, then 5 mg/day during 1 week

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tavana clinic

Full name of responsible person

Dr Hasan Solhi
Street address
Emam street,forward Valiasr hospital
City
Arak

2

Recruitment center

Name of recruitment center
Valiasr hospital
Full name of responsible person
Dr Akram Rasti
Street address
Valiasr
City
Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tavana clinic
Full name of responsible person
Dr Hasan Solhi
Street address
Emam street.forward Valiasr hospital
City
Arak
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tavana clinic
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
arak medicin univercity
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Rasti barzoki Akram
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Person responsible for scientific inquiries

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Dr Hasan Solhi
Position
Associate Professor, Technical Training Instructor
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Person responsible for updating data

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty